BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	
Pharmacist License of	)	Case No. 2012-52
MARK E. GRAZIANO	)	
License No. 16752,	)	**STATEMENT OF CHARGES**
Respondent.	)	

COMES NOW, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Director for the Iowa Board of Pharmacy (hereinafter, "Board") and files this Statement of Charges solely in his official capacity.

2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (2011).

3. On July 30, 1986, the Board issued Mark E. Graziano ("Respondent"), after examination, a license to engage in the practice of pharmacy as evidenced by license number 16752, subject to the laws of the State of Iowa and the rules of the Board.

4. Respondent's pharmacist license is current and active until June 30, 2012.

5. Respondent's address of record is 14403 Wilden Drive, Urbandale, Iowa 50323.

6. At all times material to this statement of charges, Respondent was self-employed as an owner and pharmacist in charge of Bauder Pharmacy, Inc., 3802 Ingersoll Avenue, Des Moines, Iowa 50312.

A. CHARGES

COUNT I

Respondent is charged under Iowa Code §§ 124.308(3), 124.402(1), 155A.12(4) and 155A.12(5) (2011) and 657 Iowa Administrative Code § 36.1(4)(ac) with failing to maintain adequate control over and accountability for controlled substances.

COUNT II

Respondent is charged under Iowa Code § 155A.12(1) and 657 Iowa Administrative Code § 10.15 with inadequate security and failure to establish effective controls against diversion of controlled substances.

COUNT III

Respondent is charged under Iowa Code §§ 124,306 and 155A.12(1), and 657 Iowa Administrative Code § 10.34, with failure to keep and maintain records as required by the Controlled Substances Act.

COUNT IV

Respondent is charged under Iowa Code §§ 155A.12(1), 155A.12(4) and 155A.12(5) and 657 Iowa Administrative Code § 8.9 with failure to properly sign and date invoices for controlled substances.

COUNT V

Respondent is charged under Iowa Code §§ 155A.12(1), 155A.12(4) and 155A.12(5) and 657 Iowa Administrative Code § 10.21 with dispensing Schedule II controlled substances in quantities exceeding prescriber authorization.

COUNT VI

Respondent is charged under Iowa Code §§ 155A.12(1), 155A.12(4) and 155A.12(5) and 657 Iowa Administrative Code § 10.23 with failure to comply with requirements for the partial filling of Schedule II controlled substances.

COUNT VII

Respondent is charged under Iowa Code §§ 155A.12(1), 155A.12(4) and 155A.12(5) and 657 Iowa Administrative Code § 10.33 with failure to maintain complete and accurate perpetual inventories of Schedule II controlled substances.

COUNT VIII

Respondent is charged under Iowa Code §§ 155A.12(1), 155A.12(4) and 155A.12(5) and 657 Iowa Administrative Code § 10.35 with failure to maintain a complete and accurate inventory of controlled substances.

COUNT IX

Respondent is charged under Iowa Code §§ 155A.12(1), 155A.12(4) and 155A.12(5) and 657 Iowa Administrative Code § 21.5 with failure to document verification of controlled substance refills.

COUNT X

Respondent is charged under Iowa Code § 155A.12(1) and 657 Iowa Administrative Code § 3.20 with failure to properly supervise dispensing functions that are delegated to non-pharmacists.

COUNT XI

Respondent is charged under Iowa Code § 155A.12(1) and 657 Iowa Administrative Code § 6.13 with failure to maintain complete patient records.

COUNT XII

Respondent is charged under Iowa Code § 155A.12(1) and 657 Iowa Administrative Code §§ 3.11 and 36.1(4)(aa) with failure to ensure that all pharmacy technicians have a current and active technician registration.

COUNT XIII

Respondent is charged under Iowa Code § 155A.12(1) and 657 Iowa Administrative Code § 6.2 with failure to maintain required policies and procedures for the operation of a pharmacy.

COUNT XIV

Respondent is charged under Iowa Code § 155A.12(1) and 657 Iowa Administrative Code § 6.7 with failure to provide proper security for prescription medications and pharmacy records stored in the basement.

COUNT XV

Respondent is charged under Iowa Code § 155A.12(1) and 657 Iowa Administrative Code § 8.4 with failure to wear an identification badge.

COUNT XVI

Respondent is charged under Iowa Code § 155A.12(1) and 657 Iowa Administrative Code § 8.14 with failure to have required policies, procedures and documentation for pharmacy technician training.

COUNT XVII

Respondent is charged under Iowa Code § 155A.12(1) and 657 Iowa Administrative Code § 8.26 with failure to have a continuous quality improvement program.

COUNT XVIII

Respondent is charged under Iowa Code § 155A.12(1) and 657 Iowa Administrative Code §§ 13.3, 13.6, 13.7, 13.11, 13.25, 13.27, 13.28, 13.29, and 13.31 with failure to meet minimum standards for sterile compounding.

COUNT XIX

Respondent is charged under Iowa Code § 155A.12(1) and 657 Iowa Administrative Code § 22.5 with failure to provide labeling and record keeping for patient med paks.

COUNT XX

Respondent is charged under Iowa Code §§ 155A.12(1), 155A.12(4) and 155A.12(5) and 657 Iowa Administrative Code § 36.1(4)(w) with failure to provide adequate patient counseling to patients.

B. CIRCUMSTANCES

An investigation was commenced on March 9, 2012, which revealed the following:

1. At all times material to this Statement of Charges, Respondent was self-employed as the pharmacist in charge of Bauder Pharmacy, 3802 Ingersoll Avenue, Des Moines, Iowa 50312.

2. An audit of controlled substances handled by Bauder Pharmacy between January 1, 2008, and March 21, 2012, revealed a shortage of approximately 740,888 tablets of various strengths of hydrocodone APAP, a Schedule III controlled substance. This shortage was determined by obtaining information from the Automation of Reports and Consolidated Orders System (ARCOS) maintained by the U.S. Department of Justice, Drug Enforcement Administration. ARCOS is an automated, comprehensive drug reporting system which monitors the flow of certain DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level. Respondent acquired hydrocodone products for Bauder Pharmacy from 14 different drug wholesalers between 2008 and 2012.

3. For the audit period of January 1, 2008 through March 21, 2012, ARCOS records indicate that Respondent ordered and received a total of 1,098,900 hydrocodone APAP tablets (all brands, all strengths). The majority of these hydrocodone products were of one strength; hydrocodone APAP 7.5mg/500mg (593,700 tablets).

4. For the same audit period (January 1, 2008 through March 21, 2012), prescription monitoring program (PMP) records submitted by Respondent indicate that Respondent dispensed 358,012 hydrocodone APAP tablets (all brands, all strengths) to customers.

5. For the audit period January 1, 2008 through March 21, 2012, a total of 740,888 hydrocodone APAP tablets are not accounted for in Respondent's PMP dispensing records. Respondent has received, from wholesalers, 740,888 more tablets of hydrocodone APAP than Respondent has reported selling.

6. Shortages of hydrocodone products at Bauder Pharmacy occurred as follows:
Calendar Year 2008: 229,846 tablets;
Calendar Year 2009: 163,185 tablets;
Calendar Year 2010: 155,436 tablets;
Calendar Year 2011: 182,732 tablets
January-March, 2012: 9,689 tablets.

7. Two shopper surveys in which prescriptions were filled at Bauder Pharmacy on March 8, 2012, and March 14, 2012, revealed numerous deficiencies including inadequate patient counseling, lack of patient privacy, failing to obtain required patient information, mislabeling of a prescription vial, and dispensing prescription medication in non-childproof prescription containers.

8. An inspection of Bauder Pharmacy on March 16, 2012, revealed the following additional deficiencies:
   a) Technician Higgins' registration expired on September 30, 2010, and was not renewed in a timely manner.
   b) Bauder Pharmacy has no pertinent policies and procedures as required by Board rules.
   c) Security at Bauder Pharmacy for medications and records stored in the basement was found to be inadequate (second notice).
   d) Respondent, Mark Graziano, was not wearing a badge which identified him as a pharmacist (second notice).
   e) Bauder Pharmacy's controlled substance invoices were not signed and dated.
   f) Bauder Pharmacy has no policy or documentation of technician training.
   g) Bauder Pharmacy has no continuous quality improvement program
   h) Bauder Pharmacy dispensed a Schedule II prescription in a quantity larger than what was authorized.
   i) Bauder Pharmacy partially filled schedule II prescriptions past the 72 hour limitation.
   j) Bauder Pharmacy's Schedule II perpetual inventory does not accurately reflect dispensing, resulting in negative balances.
   k) Bauder Pharmacy's Schedule II invoices were not kept separate from Schedule III, IV and V invoices.
   l) Bauder Pharmacy's annual controlled substance inventory was missing the quantity for hydrocodone w/APAP 2.5/500mg
   m) Carisoprodol was not inventoried by Bauder Pharmacy when it became a Schedule IV controlled substance on January 11, 2012.
   n) Bauder Pharmacy had no policies and procedures for sterile compounding.
   o) Bauder Pharmacy had no quality assurance program for sterile compounding.
   p) Bauder Pharmacy had no training documentation for personnel involved with sterile compounding.

q) Bauder Pharmacy had no batch records for sterile compounding and no labeling of product.
r) Bauder Pharmacy gave a longer expiration date to low risk compounded products than allowed.
s) Bauder Pharmacy has never conducted media fill testing.
t) Bauder Pharmacy's sterile compounding room has areas that need repair.
u) Bauder Pharmacy has no written cleaning procedures and no documentation of cleaning for sterile compounding areas.
v) The sterile compounding areas at Bauder Pharmacy have only been certified once a year instead of twice a year (second notice); microbial sampling has never been conducted; there were no pressure differential monitors; and there were no procedures concerning environmental requirements.
w) Bauder Pharmacy had failed to document verification of controlled substance refills for the past two years.
x) Bauder Pharmacy had no labeling or record keeping for patient med paks.
y) Bauder Pharmacy has dispensed prescriptions in containers with non child-resistant packaging without proper authorization.
z) Bauder Pharmacy has reused prescription vials.

Wherefore, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.

LLOYD K. JESSEN
Executive Director

On this 3rd day of May 2012, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.

SUSAN M. FREY, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Theresa Weeg
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

( ) personal service
( ) certified mail, return receipt requested
Article Number _____
( ) first class mail
( ) facsimile
( ) other _____

on the _____ day of May 2012.

I declare that the statements above are true to the best of my information, knowledge and belief.

_____
Jean Rhodes, Compliance Officer

BEFORE THE IOWA BOARD OF PHARMACY

Re: Pharmacist License of **MARK E. GRAZIANO** License No. 16752, Respondent.	)))))	Case No. 2012-52 **EMERGENCY ORDER**

I. JURISDICTION

The Iowa Board of Pharmacy (hereinafter, "Board") has jurisdiction over pharmacist licensees pursuant to Iowa Code Chapters 155A and 272C (2011). Mark E. Graziano (hereinafter, "Respondent") possesses Iowa pharmacist license number 16752 issued by the Board. A Statement of Charges was filed against Respondent on May 3, 2012. After receipt and review of the Statement of Charges, and careful review of evidence relating to the Statement of Charges, the Board has adopted the following Findings of Fact, Conclusions of Law and Emergency Order.

II. FINDINGS OF FACT

The Board finds as follows:

1. On July 30, 1986, the Board issued Respondent a license to engage in the practice of pharmacy as evidenced by license number 16752, subject to the laws of the State of Iowa and the rules of the Board.

2. Respondent's pharmacist license is current and active until June 30, 2012.

3. Respondent is self-employed as an owner and pharmacist in charge of Bauder Pharmacy, Inc., 3802 Ingersoll Avenue, Des Moines, Iowa 50312.

4. On or about March 9, 2012, an investigation was commenced which revealed the following:

    a. An audit of controlled substances handled by Bauder Pharmacy between January 1, 2008, and March 21, 2012, revealed a shortage of approximately 740,888 tablets of various strengths of hydrocodone APAP, a Schedule III controlled substance. This shortage was determined by obtaining information from the Automation of Reports and Consolidated Orders System (ARCOS) maintained by the U.S. Department of Justice, Drug Enforcement Administration. ARCOS is an automated, comprehensive drug reporting system which monitors the flow of certain DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level. Respondent acquired hydrocodone products for Bauder Pharmacy from 14 different drug wholesalers between 2008 and 2012.

b. For the audit period of January 1, 2008 through March 21, 2012, ARCOS records indicate that Respondent ordered and received a total of 1,098,900 hydrocodone APAP tablets (all brands, all strengths). The majority of these hydrocodone products were of one strength; hydrocodone APAP 7.5mg/500mg (593,700 tablets).

c. For the same audit period (January 1, 2008 through March 21, 2012), prescription monitoring program (PMP) records submitted by Respondent indicate that Respondent dispensed 358,012 hydrocodone APAP tablets (all brands, all strengths) to customers.

d. For the audit period January 1, 2008 through March 21, 2012, a total of 740,888 hydrocodone APAP tablets are not accounted for in Respondent's PMP dispensing records. Respondent has received, from wholesalers, 740,888 more tablets of hydrocodone APAP than Respondent has reported selling.

e. Shortages of hydrocodone products at Bauder Pharmacy occurred as follows:
Calendar Year 2008: 229,846 tablets;
Calendar Year 2009: 163,185 tablets;
Calendar Year 2010: 155,436 tablets;
Calendar Year 2011: 182,732 tablets
January-March, 2012: 9,689 tablets.

f. Two shopper surveys in which prescriptions were filled at Bauder Pharmacy on March 8, 2012, and March 14, 2012, revealed numerous deficiencies including inadequate patient counseling, lack of patient privacy, failing to obtain required patient information, mislabeling of a prescription vial, and dispensing prescription medication in non-childproof prescription containers.

g. An inspection of Bauder Pharmacy on March 16, 2012, revealed the following additional deficiencies:
   1) Technician Higgins' registration expired on September 30, 2010, and was not renewed in a timely manner.
   2) Bauder Pharmacy has no pertinent policies and procedures as required by Board rules.
   3) Security at Bauder Pharmacy for medications and records stored in the basement was found to be inadequate (second notice).
   4) Respondent, Mark Graziano, was not wearing a badge which identified him as a pharmacist (second notice).
   5) Bauder Pharmacy's controlled substance invoices were not signed and dated.
   6) Bauder Pharmacy has no policy or documentation of technician training.
   7) Bauder Pharmacy has no continuous quality improvement program
   8) Bauder Pharmacy dispensed a Schedule II prescription in a quantity larger than what was authorized.
   9) Bauder Pharmacy partially filled schedule II prescriptions past the 72 hour limitation.

10) Bauder Pharmacy's Schedule II perpetual inventory does not accurately reflect dispensing, resulting in negative balances.
11) Bauder Pharmacy's Schedule II invoices were not kept separate from Schedule III, IV and V invoices.
12) Bauder Pharmacy's annual controlled substance inventory was missing the quantity for hydrocodone w/APAP 2.5/500mg
13) Carisoprodol was not inventoried by Bauder Pharmacy when it became a Schedule IV controlled substance on January 11, 2012.
14) Bauder Pharmacy had no policies and procedures for sterile compounding.
15) Bauder Pharmacy had no quality assurance program for sterile compounding.
16) Bauder Pharmacy had no training documentation for personnel involved with sterile compounding.
17) Bauder Pharmacy had no batch records for sterile compounding and no labeling of product.
18) Bauder Pharmacy gave a longer expiration date to low risk compounded products than allowed.
19) Bauder Pharmacy has never conducted media fill testing.
20) Bauder Pharmacy's sterile compounding room has areas that need repair.
21) Bauder Pharmacy has no written cleaning procedures and no documentation of cleaning for sterile compounding areas.
22) The sterile compounding areas at Bauder Pharmacy have only been certified once a year instead of twice a year (second notice); microbial sampling has never been conducted; there were no pressure differential monitors; and there were no procedures concerning environmental requirements.
23) Bauder Pharmacy had failed to document verification of controlled substance refills for the past two years.
24) Bauder Pharmacy had no labeling or record keeping for patient med paks.
25) Bauder Pharmacy has dispensed prescriptions in containers with non child-resistant packaging without proper authorization.
26) Bauder Pharmacy has reused prescription vials.

III. CONCLUSIONS OF LAW

1. The Board concludes that the evidence assembled during the investigation of Respondent supports the May 3, 2012, Statement of Charges against Respondent. The Board also concludes that Respondent (a) cannot provide accountability for 740,888 doses of hydrocodone APAP, a Schedule III controlled substance; (b) cannot assure patient safety in connection with sterile compounds that are prepared at Bauder Pharmacy; and (c) has failed to meet the minimum standards for the safe practice of pharmacy.

2. The Board concludes that Respondent is an immediate danger to the public health, safety and welfare for the following reasons:

a. For the audit period January 1, 2008 through March 21, 2012, a total of 740,888 hydrocodone APAP tablets, shipped to Respondent by wholesalers, are not accounted for by Respondent's PMP records of prescription sales.

b. The void in Respondent's dispensing (PMP) records indicates that, for the audit period January 1, 2008 through March 21, 2012, approximately 740,888 hydrocodone APAP tablets were dispensed in violation of the provisions of Iowa Code chapter 124 and 155A (2011).

c. Hydrocodone with APAP and hydrocodone with IBU are addictive Schedule III controlled substances, frequently distributed illegally. The Iowa legislature has determined that hydrocodone APAP use may lead to moderate physical dependence and high psychological dependence. Iowa Code § 124.207 (2011).

d. Illegal distribution of large quantities of hydrocodone products represents a threat to the public health and safety due to the addictive nature of the drug. The assembled evidence indicates that Respondent has engaged in a steady, repeated practice of illegal hydrocodone APAP distribution over a period of more than four years. The amount of hydrocodone APAP not accounted for in Respondent's pharmacy records – 740,888 hydrocodone APAP tablets – is very large considering the moderate size of Respondent's pharmacy and the emphasis the Board places on accurate record keeping and security of controlled substances. Approximately two thirds of the hydrocodone APAP being purchased by Respondent's pharmacy is not accounted for in the PMP records being reported by Respondent. There is no likelihood that the discrepancy between wholesaler shipping records and Respondent's dispensing records can be explained as a simple record-keeping error.

e. Sterile products must be prepared in a manner which ensures product efficacy and patient safety. Respondent has failed to meet the minimum standards for the preparation of sterile products.

f. Prescriptions must be filled and dispensed in a manner which provides adequate labeling, packaging, and patient counseling. Patient health information must also be sufficient to allow drug use review. Respondent has placed the public at risk by failing to comply with all applicable minimum standards.

3. The Board concludes that immediate, emergency action must be taken for the reason that if Respondent is allowed to continue to work as a pharmacist, the public health, safety and welfare will be threatened by Respondent's actions. Given this conclusion, the Board must act in the interest of the public to suspend Respondent's license to practice pharmacy.

4. The Board concludes that Respondent has failed to comply with minimum standards for the practice of pharmacy and is an immediate danger to the public health, safety and welfare, and further concludes that the minimum emergency action needed to protect the public health, safety and welfare is an immediate suspension of Respondent's pharmacist license.

5. The provisions of Iowa Code § 17A.18A (2011) permit the Iowa Board of Pharmacy to take emergency action to protect the health, safety and welfare of the public. A basis for emergency action against Respondent, pursuant to the provisions of the Iowa Code and the Iowa Administrative Code, has been established by the findings of fact adopted above.

IV. EMERGENCY ORDER

The Board ORDERS as follows:

1. Pursuant to Iowa Code § 17A.18A and Iowa Code chapter 155A (2011), and 657 Iowa Administrative Code § 36.1(4)(b), the pharmacist license of MARK E. GRAZIANO is suspended indefinitely upon service. This suspension is effective immediately upon service of this order.

2. Respondent shall be notified of this order as provided in 657 Iowa Administrative Code 35.30(2).

3. A hearing regarding this Emergency Adjudicative Order and the Statement of Charges against Respondent shall be held on June 26, 2012. The hearing will commence at 9:00 A.M. and be held at the office of the Iowa Board of Pharmacy, 400 Southwest 8th Street, Suite E, Des Moines, Iowa 50309.

DATED this 3rd day of May 2012.

Susan M. Frey

SUSAN M. FREY, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Theresa Weeg
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

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PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

( ) personal service
( ) certified mail, return receipt requested
Article Number _____
( ) first class mail
( ) facsimile
( ) other _____

on the _____ day of May 2012.

I declare that the statements above are true to the best of my information, knowledge and belief.

_____
Jean Rhodes, Compliance Officer